



AUG 1 2011

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In Re: Patent Term Extension
Application for
U.S. Patent No. 7,060,250

NOTICE OF FINAL DETERMINATION AND REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. 7,060,250, claims of which cover the human drug product ABLAVAR® (gadofosveset trisodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 923 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

Applicant also has applied for patent term extension of U.S. Patent No. 6,676,929 based on the regulatory review period for ABLAVAR® (gadofosveset trisodium).

When patent term extension applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance, unless applicant elects a different patent. In the absence of an election by applicant within one month of the date of this notice of the present patent, and in accordance with 37 CFR 1.785(b), the application for patent term extension in U.S. Patent No. 7,060,250 will be denied. Accordingly, the application for patent term extension of the patent having the earlier date of issuance will be granted, i.e., a certificate of extension will be issued to U.S. Patent No 6,676,929. In the absence of a request for reconsideration, and if U.S. Patent No. 7,060,250 is elected, the Director will issue to the applicant a certificate of extension, under seal, for a period of 923 days in U.S. Patent No. 7,060,250.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of June 8, 2010 (75 Fed. Reg. 32479). Under 35 U.S.C. § 156(c):

$$\text{Period of Extension} = \text{RRP} - \text{PGRRP} - \text{DD} - \frac{1}{2} (\text{TP} - \text{PGTP})^1$$

¹ Consistent with 35 U.S.C. § 156(c), "RRP" is the total number of days in the regulatory review period, "PGRRP" is the number of days of the RRP which were on and before the date on which the patent issued, "DD" is the number of days of the RRP that the applicant did not act

$$\begin{aligned} &= 4,508 - 3,585 - 0 - \frac{1}{2} (2,673 - 2,673) \\ &= 923 \text{ days (2.5 years)} \end{aligned}$$

Since the regulatory review period began August 21, 1996, before the patent issued June 13, 2006), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From August 21, 1996, to and including December 15, 2003, is 2,673 days, and from and including December 15, 2003, through and including June 13, 2006, is 912 days for a total of 3,585 days; this period is subtracted from the number of days according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	7,060,250
Granted:	June 13, 2006
Original Expiration Date ² :	May 26, 2015
Applicant:	Thomas J. McMurry et al.
Owner of Record:	Lantheus Medical Imaging, Inc.
Title:	Diagnostic Imaging Contrast Agents With Extended Blood Retention
Product Trade Name:	ABLAVAR® (gadofosveset trisodium)
Term Extended:	923 days
Expiration Date of Extension:	December 4, 2017

with due diligence, "TP" is the testing phase period described in paragraphs (1)(B)(i), (2)(B)(i), (3)(B)(i), (4)(B)(i), and (5)(B)(i) of subsection (g) of 35 U.S.C. § 156, and "PGTP" is the number of days of the TP which were on and before the date on which the patent issued, wherein half days are ignored for purposes of the subtraction of $\frac{1}{2}$ (TP - PGTP).

²Subject to the provisions of 35 U.S.C. § 41(b).

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE By FAX: (571) 273-7755
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.



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Office of the Associate Commissioner
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cc: Office of Regulatory Policy
Food and Drug Administration
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Silver Spring, MD 20993-0002

RE: ABLAVAR® (gadofosveset
trisodium)
Docket No.: FDA-2009-E-0165

Attention: Beverly Friedman